respectively.

02 cont

15. (Once Amended) A method of treating sexual dysfunction, which comprises administering a sustained release formulation, as defined in claim 31, to a mammal in need of such treatment.

03

17. (Once Amended) A method of improving sexual function in a mammal, which comprises administering a sustained release formulation, as defined in claim 31, to the mammal.

04

19. (Once Amended) A method of increasing the probability of a nocturnal erection in a male mammal, which comprises administering a sustained release formulation, as defined in claim 31, to the male mammal.

05

21. (Once Amended) A product containing a controlled-release formulation comprising a cGMP PDE-5 inhibitor and a cGMP PDE-5 inhibitor in immediate release form, as a combined preparation for simultaneous, separate or sequential use in the treatment of sexual dysfunction.

REMARKS

Claims 31 to 53 are in the application, claims 1-30 having been canceled.

The Examiner indicated that claims 31-41, 43, and 52 are allowed. That indication is acknowledged with gratitude.

Claims 42, 44-51, and 53 stand rejected under §112 and §102(e), for reasons indicated in the Office Action. After consideration of the Office Action, the above amendments have been made, *inter alia*, to obviate the rejections and/or to otherwise place the application in condition for allowance. Sheets captioned "VERSION MARKED UP TO SHOW CHANGES MADE" are attached hereto to show the exact nature of the emendations.

Claims 46, 47, and 53 stand rejected as being non-enabling under §112, the

Examiner having objected to inclusion of the term "prevention". It is believed that the rejection is inapplicable as applied to claim 46 since no mention of "prevention" was made in that claim in the first place. Although Applicants do not agree with the rejection otherwise, "prevention" has been removed from claims 47 and 53. By these amendments, it is respectfully submitted that the non-enablement rejection under §112 has been obviated, and withdrawal of same is respectfully requested.

Claims 42 and 46 stand rejected under §112 as indefinite, the Examiner having singled out the use of the terminology "also includes" rather than "further comprises". In response, Applicants have implemented the Examiner's suggestion by replacing "includes" language with "comprises", as appropriate. Withdrawal of the indefiniteness rejection under §112 is accordingly respectfully requested.

Claims 44 through 51 stand rejected under §102(e) as anticipated by Sui, U.S. 6,077,841. To obviate the rejection, Applicants have (1) canceled claims 44 and 45 without waiver or prejudice and (2) made the remaining claims, directly or indirectly, dependent from claim 31 which the Examiner indicated to be allowed. By being dependent from an allowed claim, claims 46-51 are themselves allowable, it being additionally noted that Sui discloses no such formulations. Accordingly, withdrawal of the rejection under §112 is respectfully requested.

No other issues remain for consideration in this application.

Accordingly, in view of the foregoing comments and amendments, it is respectfully submitted that this application is in condition for allowance. A Notice of allowance is respectfully requested.

Respectfully submitted,

Date: JAN. 15, 2003

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VERSION MARKED UP TO SHOW CHANGES MADE

42. (Once Amended) A formulation as claimed in claim 41, wherein the core further comprises ~~also includes~~ a buffering agent.

Cancel claims 44 and 45 without waiver or prejudice.

46. (Once Amended) A process for the production of a sustained-release formulation comprising a cGMP PDE-5 inhibitor embedded in a matrix from which it is released by diffusion or erosion, which comprises ~~includes~~ the steps of:

(a) mixing the cGMP PDE-5 inhibitor with a matrix material, and pressing into tablets;

(b) forming a core comprising the cGMP PDE-5 inhibitor and then coating the core with a release rate-controlling membrane; or

(c) forming a core containing the cGMP PDE-5 inhibitor and then coating the core with a coating impermeable to the cGMP PDE-5 inhibitor;

respectively.

47. (Once Amended) A method of treating ~~or preventing~~ sexual dysfunction, which comprises administering a sustained release ~~controlled-release~~ formulation, as defined in claim 31, ~~comprising a cGMP PDE-5 inhibitor~~ to a mammal in need of such treatment ~~or prevention~~.

49. (Once Amended) A method of improving sexual function in a mammal, which comprises administering a sustained release ~~controlled-release~~ formulation, as defined in claim 31, ~~comprising a cGMP PDE-5 inhibitor~~ to the mammal.

51. (Once Amended) A method of increasing the probability of a nocturnal erection in a male mammal, which comprises administering a sustained release ~~controlled-release~~ formulation, as defined in claim 31, ~~comprising a cGMP PDE-5 inhibitor~~ to the male mammal.

53. (Once Amended) A product containing a controlled-release

formulation comprising a cGMP PDE-5 inhibitor and a cGMP PDE-5 inhibitor in immediate release form, as a combined preparation for simultaneous, separate or sequential use in the treatment ~~or prevention~~ of sexual dysfunction.